

## REMARKS

The office action and references cited therein have been carefully considered together with the present application and claim 11 has been corrected in the manner suggested. Also, Figs. 2 and 3 have been corrected to indicate that they illustrate prior art and the specification has been amended to insert the heading "Summary of the Invention" and "Description of the Drawings" as required by the examiner.

Apart from the correction of the grammatical error of claim 11, the claims have not been amended because it is believed that all of the pending claims are neither anticipated, taught nor suggested by Lewis, applied singularly or in combination with the Baxter reference as well as the references that are of record. While the examiner has provided extensive comments concerning Lewis, it is clear that neither Lewis nor Baxter meet several features of the claims. The extensive characterization of the Lewis reference ignores the advances that are represented by the present invention over the prior art. It is noted that Lewis is assigned to Clintec Nutrition Co. which is related to the assignee of the present invention. The present invention significantly advances the state of the art and includes features and functionality that are totally missing in Lewis and Baxter. The examiner has underlined the word "incompatible" several times during the characterization of the Lewis reference as if the knowledge that some drugs are not compatible with one another is significant to the present invention. If that was what was intended, the examiner has completely missed the point of the present invention.

More specifically, and referring to claim 1, apparatus is claimed for use in controlling the operation of at least one pharmaceutical compounder which comprises, inter alia, "computing means memory means for storing instructions for operating the apparatus and for controlling the compounders to prepare a prescribed admixture, said memory means including data relating to a plurality of pharmaceutical components" and wherein "said computing means being adapted to receive a prescription admixture, identify the pharmaceutical components thereof, determine the compatibility of pharmaceutical components relative to one another, determine the order in which the components are transferred in preparing the prescribed admixture". As is clearly set forth in the claim, the computing means performs these functions, not a technician or operator. As is set forth in the specification, data relating to the pharmaceutical components is stored in the memory means and is used by the computing means to identify the pharmaceutical components, determine their compatibility relative to one another and determine the order in which the components are transferred in preparing the prescription admixture. This is done in the course of its operation. Lewis simply does none of this. The Lewis apparatus must be programmed by an operator using a keyboard and possibly another computer, but neither the microprocessor nor the pumping microprocessor is adapted to identify the specific pharmaceutical components or determine their compatibility or the order in which the components are transferred. To the extent that compatibility or incompatibility of components is of concern, it comes from the operator.

The only enlightenment occurs at column 31, lines 7-10 where it states “normally, a rinse will not be conducted unless the next fluid to be pumped is incompatible with the previous fluid, or if the previous fluid pumped was the last fluid to be pumped.” In the rinse operation discussion at column 31, lines 58-64, it is clear that rinsing is operator defined: “As can be seen in Fig. 37, the first function performed during the rinsing operation is to perform a check to determine if the chamber needs to be rinsed after fluid has been transmitting from a particular source container. An operator of the device may indicate that a rinse is required when information is being entered into the device”.

There is little discussion as to the order in which components are transferred. Presumably, the order can be controlled, but it is done by an operator during setup. At column 20, lines 7-10, it states “the keyboard programming mode is the mode in which an operator can input information into the device to cause the device to transfer specific amounts of fluid from specific individual source containers in the receiving container.” Also, at column 21, lines 13-20, the operation is described: “the programmer may then use the keyboard illustrated in Fig. 22 to program the amount of fluid to be transferred from that particular source container to the receiving container. The programmer may either enter the volume or the specific gravity of the fluid to be transferred. Typically, during initial setup of the device, the specific gravity for each source container will be initially programmed by the operator.” And finally, at column 21, lines 45-47, “after the operator has completed entering information into the device for

all the source containers, the operator may then press the start key 284.” It is clear that the Lewis apparatus only operates in a particular manner that is established by the operator programming its operation. The operator keys in components and presumably their order as a result of operator knowledge of compatibility or incompatibility of components relative to one another determines the order in which they are transferred and if the operator believes that a rinse should be done, programs that as well. The Baxter reference does not supply these deficiencies. For the above reasons, claim 1 is neither anticipated, taught nor suggested by Lewis, Baxter, applied singularly or in combination with any of the other references of record.

Independent claim 24 is directed to a method for controlling the operation of at least one pharmaceutical compounder wherein the method utilizes a computing means having memory means for storing, *inter alia*, data relating to a plurality of pharmaceutical components that may be transferred to prepare the prescription admixture and which comprises the steps of identifying and determining the amounts of the pharmaceutical components of the prescription admixture, determining the compatibility of the pharmaceutical components relative to one another as well as the step of determining the order in which the components are transferred during the preparation of the prescription admixture. The computing means performs these identifying and determining steps. Lewis simply does not perform these steps. To the extent that they are carried out at all, they are carried out by an operator and certainly not by the

microprocessors in the Lewis system. For these reasons as well as the reasons more fully described with regard to claim 1, it is believed that claim 24 is neither anticipated, taught nor suggested by Lewis or Baxter, applied singularly or in combination with one another or with the other references of record.

Claims 2-23 and 25-31 necessarily include the features of the independent claims from which they depend in addition to describing features and functionality that are not part of those claims and are therefore believed to be allowable.

Additionally, claim 2 recites the functionality that the computing means is adapted to convert the amount of each component to a measure in which the compounder that is to prepare the prescription and mixture is able to transfer. This is simply not taught or suggested by Lewis. Lewis is a self-contained system which requires inputting that is done by a keyboard entry device. The only reference to another source is that "another method of entering the information into the device is through a computer terminal . . .", column 19, lines 14-21. The functionality of claim 2 is not addressed and therefore cannot be taught or suggested by Lewis, Baxter or any of the other references of record.

The functionality of claim 3 recites that the computing means is adapted to convert amounts of component volume set forth in the prescription admixture to a weight measure by multiplying the specific gravity of the component by the volume set forth in the prescription admixture. Lewis is not believed to teach or suggest this feature for the

reason that an operator either inputs volume or specific gravity information into the apparatus during initial setup of the apparatus (column 21, lines 15-18).

The functionality or features of claim 4 are also not taught or suggested by any of the references of record. Neither Lewis nor Baxter have data relating to a plurality of pharmaceutical components that comprise a database having a plurality compatibility groups as well as data specifying the compatibility and/or incompatibility of each group with respect to the other groups. It is simply not present or suggested.

Claim 5 further recites that at least the first one of the compatibility groups comprises components which include lipids and the second one of said compatibility groups comprises a component that is sterile water. Again neither Lewis nor Baxter have a database, much less a database that suggests these characteristics.

With regard to claim 6, neither Lewis nor Baxter even remotely teach or suggest the computing means determining the order in which components are transferred so that the order is in accordance with a set of general rules of order of admixing as specified in this claim.

Claim 7 further specifies the features and functionality of the computing means determining the number and location of rinses that are to be made during the order of transfer of components. It simply is not taught or suggested by Lewis or any of the other references of record.

Claim 9 specifies further functionality relating to the order of transfer that Lewis or Baxter simply do not address and therefore cannot teach or suggest.

Claim 13 cites additional functionality wherein the computing means is adapted to examine the prescription admixture and determine whether lipid components are a part of it as well as making other determinations as recited. Neither Lewis, Baxter nor any of the other references even remotely teach or suggest this functionality.

Claim 14 describes the functionality of the computing means being adapted to receive a plurality of prescription admixtures and to order them into a queue for preparation and to reorder them based upon commonality of predetermined components as recited in the claim. Neither Lewis, Baxter nor any of the other references of record even remotely teach or suggest this functionality.

Claim 15 recites that the computing means is adapted to retrieve data relating to a patient profile as well as data relating to a plurality of categories of patients and make comparisons as recited in the claims. Lewis and Baxter simply do not have this capability and therefore cannot teach or suggest this claim.

With regard to claim 18, it is believed that Lewis and Baxter do not teach or suggest preparing a report containing the information as set forth in this claim.

With regard to claim 19-23, it is also believed that none of the references of record teach or suggest this functionality.


With regard to claim 25, it is believed allowable for the same reasons that claim 2 is allowable. Claim 26 is believed allowable for the same reasons that claim 4 is allowable. Claim 27 is believed allowable because neither Lewis nor Baxter teach or suggest determining the order of admixing components.

Claim 28 is believed allowable for the same reasons that claim 6 is allowable. Claim 29 is believed allowable for the reason that neither Lewis nor Baxter teach or suggest an order determining step and particularly the functionality described in this claim. With regard to claims 30 and 31, the functionality set forth therein are not remotely taught or suggested by any of these references of record.

For the many foregoing reasons, reconsideration and allowance of all claims presently pending in the application is respectfully requested.

Respectfully submitted,

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